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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/778,392	02/06/2001	Stefan G. Schreck	ECV-5620	4519

30452 7590 02/05/2004

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EXAMINER	
ODLAND, KATHRYN P	

ART UNIT	PAPER NUMBER
3743	13

DATE MAILED: 02/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/778,392	SCHRECK ET AL.
	Examiner	Art Unit
	Kathryn Odland	3743

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Amendment

This is a response to the amendment dated December 12, 2003. Claims 1-52 are pending. The amendments to the specification and drawings are acknowledged.

Response to Arguments

1. Applicant's arguments, see Paper 12, filed December 12, 2003, with respect to the rejection(s)of claim(s) 1-52 under Ferrari et al. (US Patent No. 6,190,357) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Sterman et al. in US Patent No. 5,814,097.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claim 5 recites the limitation "the two pieces of tissue" in line 2. There is insufficient antecedent basis for this limitation in the claim.

4. Claim 23 recites the limitation "the tissue" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 2, 5-7, 10, 20, 23-35, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Sterman et al. in US Patent No. 5,814,097.

Regarding claims 1 and 30, Sterman et al. disclose Ferrari et al. disclose a system/method for performing a surgical procedure within a blood vessel, having at least one guidewire, as recited in column 15, lines 55-60 and column 16, lines 20-25, the guidewire is inserted into a body vessel; an antegrade probe having a distal portion and at least one antegrade guidewire lumen, the antegrade guidewire lumen terminating in at least one guidewire port (necessarily), as recited in throughout the specification with emphasis on columns 15-16 and more particularly column 15, lines 55-60; a retrograde probe having a distal portion, the retrograde probe having at least one retrograde guidewire lumen the retrograde guidewire lumen terminating in at least one retrograde guidewire port (necessarily), as recited in throughout the specification with emphasis on columns 15-16 and more particularly column 16, lines 8-25, where the at least one retrograde guidewire port is co-aligned with the antegrade probe, as clearly shown in figure 34A; and at least one of the antegrade probe and the retrograde probe further comprising at least one lumen in addition to the retrograde and antegrade guidewire lumens, as recited in column 3, lines 60-65, column 5, lines 15-40 and 59-65, columns 15-16, column 18, lines 35-50, and column 19, lines 18-35.

Regarding claim 2, Sterman et al. disclose that as applied to claim 1, as well as, an antegrade probe and retrograde probe that are placed over the guidewire so that the guidewire resides within the at least one antegrade guidewire port and the at least one retrograde guidewire port and wherein the at least one retrograde guidewire port is co-aligned with the at least one antegrade guidewire port, as recited throughout the specification with emphasis on columns 15-16 and clearly seen in figure 34A.

Regarding claim 5, Sterman et al. disclose that as applied to claim 1, as well as, an antegrade probe and the retrograde probe that are each engageable with one of two pieces of tissue, to stabilize the tissue pieces, as seen in figure 34A.

Regarding claim 6, Sterman et al. disclose that as applied to claim 5, as well as, an antegrade probe and retrograde probe that are mutually engageable with the two pieces of tissue to stabilize the tissue pieces interposed therebetween, as recited throughout the specification and seen in figure 34A, for example.

Regarding claim 7, Sterman et al. disclose that as applied to claim 1, as well as, at least one lumen comprises a vacuum lumen, as recited in column 5, lines 20-35, column 15, lines 53-67, and column 19, lines 18-35.

Regarding claim 10, Sterman et al. disclose that as applied to claim 1, as well as, at least one of the distal portion of at least one of the antegrade probe and the retrograde probe that is substantially perpendicular to the longitudinal axis of the antegrade or retrograde probe, as recited throughout the specification and dependent on where it is in the deployment process, etc.

Regarding claim 20, Sterman et al. disclose that as applied to claim 1, as well as, at least one of the antegrade probe distal portion and the retrograde probe distal portion disposes at least one deployable alignment mechanism, as recited throughout the specification and wherein even a guidewire can be considered an alignment mechanism.

Regarding claim 23, Sterman et al. disclose that as applied to claim 1, as well as, at least one of the antegrade probe and retrograde probe having sufficient length, steerability and maneuverability to reach a tissue from a peripheral insertion site, as recited throughout the specification and seen in the drawings.

Regarding claim 24, Sterman et al. disclose that as applied to claim 23, as well as, a peripheral insertion site that is the femoral artery (84), as recited in column 15, lines 53-67.

Regarding claim 25, Sterman et al. disclose that as applied to claim 23, as well as, a peripheral insertion site that is the brachial artery, as recited in column 15, lines 53-67.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sterman et al. in US Patent No. 5,814,097.

Regarding claim 3, Sterman et al. disclose that as applied to claim 1. However, Sterman et al. does not explicitly recite a second guidewire and wherein the antegrade probe comprises a first antegrade guidewire lumen terminating in a first antegrade guidewire port and a second antegrade guidewire lumen terminating in a second antegrade guidewire port and the retrograde probe comprises a first retrograde guidewire lumen terminating in a first retrograde guidewire port and a second retrograde guidewire lumen terminating in a second retrograde guidewire port. On the other hand, Ferrari et al., in column 5, lines 15-65 and column 19, lines 18-35 discuss that any number of lumens can be formed in the tubular body and that the additional lumens can be for tool access. Therefore, it is within the scope of the invention and obvious to one with ordinary skill in the art to provide the system of Sterman et al with a second

guidewire, wherein the antegrade probe has a first antegrade guidewire lumen terminating in a first antegrade guidewire port and a second antegrade guidewire lumen terminating in a second antegrade guidewire port where the retrograde probe has a first retrograde guidewire lumen terminating in a first retrograde guidewire port and a second retrograde guidewire lumen terminating in a second retrograde guidewire port for the purpose of enhanced alignment with additional guidewires.

Regarding claim 4, Sterman et al. as modified disclose that as applied to claim 3. However, Sterman et al. do not explicitly recite a first guidewire that resides within the first antegrade guidewire lumen and the first retrograde guidewire lumen and the second guidewire resides in the second antegrade guidewire lumen and the second retrograde guidewire lumen to align the distal portion of the antegrade probe with the distal portion of the retrograde probe. On the other hand, it would be obvious to one with ordinary skill in the art to use multiple guidewires to assure proper placement of the device and given the co-alignment having them interact would further be obvious to one with ordinary skill in the art.

9. Claims 8, 9, 11, 26-28, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sterman et al. in US Patent No. 5,814,097 in view of Ferrari et al. in US Patent No. 6,190,357.

Regarding claims 8 and 9, Sterman et al. disclose that as applied to claim 7. However, Sterman et al. do not explicitly recite at least one vacuum lumen

that terminates in at least one vacuum port at the distal portion of the antegrade/retrograde probe, thereby enabling the grasping and manipulation of tissue. On the other hand, Ferrari et al. teach at least one vacuum lumen that terminates in at least one vacuum port at the distal portion of a probe for tissue manipulation, in column 18, lines 55-60, and column 20, lines 36-46. Therefore, it would be obvious to one with ordinary skill in the art to modify the system of Sterman et al. to include at least one vacuum lumen that terminates in at least one vacuum port at the distal portion of the antegrade/retrograde probe that enables tissue manipulation for the purpose of properly grasping the valve.

Regarding claim 11, Sterman et al. disclose that as applied to claim 1. However, Sterman et al. do not explicitly recite a distal portion of at least one the antegrade probe and the retrograde probe that is tapered. On the other hand, Ferrari et al. teach a taper, as seen in figure 22. Thus, it would be obvious to one with ordinary skill in the art to modify the invention of Sterman et al. to include a taper for the purpose of enhanced access and vacuum.

Regarding claim 26, 27, and 37, Sterman et al. disclose that as applied to claim 1 and as modified claim 36. However, Sterman et al. do not explicitly recite a steering mechanism located proximate to the distal portion of at least one of the antegrade probe and the retrograde probe and a steering conduit attached to the distal portion of at least one of the antegrade probe and the retrograde probe,

the steering conduit in communication with an operator through one of the at least one antegrade lumen and the at least one retrograde lumen. On the other hand, Ferrari et al. teach a steering mechanism located proximate to the distal portion of at least one of the antegrade probe and the retrograde probe, as recited in column 19, lines 15-42 and a steering conduit attached to the distal portion of at least one of the antegrade probe and the retrograde probe, the steering conduit in communication with an operator through one of the at least one antegrade lumen and the at least one retrograde lumen. Thus, it would be obvious to one with ordinary skill in the art to modify the invention of Sterman et al. to include a steering mechanism for the purpose of enhanced movement control.

Regarding claim 28, Sterman et al. disclose that as applied to claim 1. However, Sterman et al. do not recite at least one echogenic member at or near the distal portion of one of the antegrade probe and the retrograde probe to enhance echo visualization. On the other hand, Ferrari et al. teach at least one echogenic member at or near the distal portion of one of the antegrade probe and the retrograde probe to enhance echo visualization, as recited in column 21, lines 1-3. Thus, it would be obvious to one with ordinary skill in the art to modify the invention of Sterman et al. to include at least one echogenic member at or near the distal portion of one of the antegrade probe and the retrograde probe, as taught by Ferrari et l. for the purpose of enhancing echo visualization.

10. Claims 8, 9, 12-19, 21, 22, and 26-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sterman et al. in US Patent No. 5,814,097 in view of St. Goar et al. in US Patent No. 6,629,534.

Regarding claims 8 and 9, Sterman et al. disclose that as applied to claim 7. However, Sterman et al. do not explicitly recite at least one vacuum lumen that terminates in at least one vacuum port at the distal portion of the antegrade/retrograde probe, thereby enabling the grasping and manipulation of tissue. On the other hand, St. Goar et al. teach at least one vacuum lumen that terminates in at least one vacuum port at the distal portion of a probe for tissue manipulation, in column 9, lines 30-41, for example. Therefore, it would be obvious to one with ordinary skill in the art to modify the system of Sterman et al. to include at least one vacuum lumen that terminates in at least one vacuum port at the distal portion of the antegrade/retrograde probe that enables tissue manipulation for the purpose of properly grasping the valve.

Regarding claims 12, Sterman et al. disclose that as applied to claim 1. However, Sterman et al. do not explicitly recite at least one tissue fastener at the distal end of either the retrograde probe or the antegrade probe. On the other hand, St. Goar et al. teach at least one tissue fastener at the distal end of either the retrograde probe or the antegrade probe, as recited throughout the specification and abstract, column 4, lines 9-20, etc. Thus, it would be obvious to

one with ordinary skill in the art to modify the invention of Sterman et al. to include at least one tissue fastener at the distal end of either the retrograde probe or the antegrade probe, as taught by St. Goar et al. for the purpose of less invasive procedures.

Regarding claims 13-19 and 32-35, Sterman et al. discloses that as applied to claim 1 and as modified that as applied to claims 12, 17, 18, and 31. However, Sterman et al. do not recite a tissue fastener that is a suture-based tissue fastener; a tissue fastener that is a clip; a tissue fastener that is a staple; a tissue fastener receiver, the receiver providing cooperative stabilization of tissue while affixing the tissue fastener; at least one lumen comprises a tissue fastening lumen; at least one tissue fastener at the distal end of either the retrograde probe or the antegrade probe; and a tissue fastener that is a needle and suture. On the other hand, St. Goar et al. teach a tissue fastener that is a suture-based tissue fastener; a tissue fastener that is a clip; a tissue fastener that is a staple; a tissue fastener receiver, the receiver providing cooperative stabilization of tissue while affixing the tissue fastener; at least one lumen comprises a tissue fastening lumen; at least one tissue fastener at the distal end of either the retrograde probe or the antegrade probe; and a tissue fastener that is a needle and suture, as discussed throughout the specification. Thus, it would be obvious to one with ordinary skill in the art to modify the invention of Sterman et al. to include at least one tissue fastener that is a suture-based tissue fastener; a tissue fastener that is

a clip; a tissue fastener that is a staple; a tissue fastener receiver, the receiver providing cooperative stabilization of tissue while affixing the tissue fastener; at least one lumen comprises a tissue fastening lumen; at least one tissue fastener at the distal end of either the retrograde probe or the antegrade probe; and a tissue fastener that is a needle and suture, as taught by St. Goar et al. for the purpose of less invasive procedures.

Regarding claim 21, Sterman et al. discloses that as applied to claim 20. However, Sterman et al. do not recite at least two alignment arms flexibly attached to the distal portion of at least one of the antegrade probe and the retrograde probe; a deployment conduit operably connected to the at least two alignment arms; the deployment conduit attached to a deployment actuator; the at least two alignment arms having a retracted position wherein the arms are located proximal to the distal portion of at least one of the antegrade probe and the retrograde probe; the at least two alignment arms having a deployed position wherein the arms are extended radially from the distal portion of at least one of the antegrade probe and the retrograde probe; and the retracted and deployed positions achieved through manipulation of the deployment actuator. On the other hand, St. Goar et al. teach at least two alignment arms (such as 800, for example) flexibly attached to the distal portion of at least one of the antegrade probe and the retrograde probe; a deployment conduit (801) operably connected to the at least two alignment arms; the deployment conduit attached to a

deployment actuator; the at least two alignment arms having a retracted position wherein the arms are located proximal to the distal portion of at least one of the antegrade probe and the retrograde probe; the at least two alignment arms having a deployed position wherein the arms are extended radially from the distal portion of at least one of the antegrade probe and the retrograde probe; and the retracted and deployed positions achieved through manipulation of the deployment actuator, as seen in figures 47A-47D, for example. Thus, it would be obvious to one with ordinary skill in the art to modify the invention of Sterman et al. to include at least one the tissue fastener mentioned above, as taught by St. Goar et al. for the purpose of less invasive procedures.

Regarding claim 22, Sterman et al. as modified discloses that as applied to claim 21. Further, St. Goar et al. teach an alignment mechanism deployment lumen, wherein numerous tools function as alignment tools as recited throughout the specification.

Regarding claim 26, 27, and 37, Sterman et al. disclose that as applied to claim 1 and as modified claim 36. However, Sterman et al. do not explicitly recite a steering mechanism located proximate to the distal portion of at least one of the antegrade probe and the retrograde probe or a steering conduit attached to the distal portion of at least one of the antegrade probe and the retrograde probe, the steering conduit in communication with an operator through one of the at

least one antegrade lumen and the at least one retrograde lumen. On the other hand, St. Goar et al. teach a steering mechanism, as recited in column 3, lines 50-55. Thus, it would be obvious to modify the invention of Sterman et al. to have a steering mechanism as taught by St. Goar et al. for the purpose of enhanced movement and more precise location. This modification would necessarily yield a steering mechanism located proximate to the distal portion of at least one of the antegrade probe and the retrograde probe and a steering conduit attached to the distal portion of at least one of the antegrade probe and the retrograde probe, the steering conduit in communication with an operator through one of the at least one antegrade lumen and the at least one retrograde lumen.

Regarding claim 28, Sterman et al. disclose that as applied to claim 1. However, Sterman et al. do not recite at least one echogenic member at or near the distal portion of one of the antegrade probe and the retrograde probe to enhance echo visualization. On the other hand, St. Goar et al. teach at least one echogenic member at or near the distal portion of one of the antegrade probe and the retrograde probe to enhance echo visualization, as discussed throughout the specification. Thus, it would be obvious to one with ordinary skill in the art to modify the invention of Sterman et al. to include at least one echogenic member at or near the distal portion of one of the antegrade probe and the retrograde

probe, as taught by St. Goar et al. for the purpose of enhancing echo visualization.

Regarding claim 29, Sterman et al. disclose that as applied to claim 1. However, Sterman et al. do not recite a polymer coating, which can be wholly or selectively applied at or near the distal portion of one of the antegrade probe and the retrograde probe to enhance echo visualization. On the other hand, St. Goar et al. teach to enhance echo visualization. Thus, it would be obvious when modifying the invention of Sterman et al. to enhance echo visualization to include a polymer coating as a known way of enhancing echo visualization.

Regarding claim 31, Sterman et al. disclose the subject matter as applied to claim 1 and as it applied to corresponding part of claim 31. However, Sterman et al. do not explicitly at least one tissue fastener at the distal end of either the retrograde probe or antegrade probe. On the other hand, St. Goar et al. teach tissue fasteners. Thus, it would be obvious to one with ordinary skill in the art to modify the invention of Sterman et al. to include a tissue fastener at the distal end of either the retrograde probe or antegrade probe, as taught by St. Goar et al. for the purpose of performing less invasive procedures.

Regarding claim 36, Sterman et al. disclose the subject matter as applied to claim 1 and as it applied to corresponding part of claim 36. However, Sterman

et al. do not explicitly recite a steering mechanism located proximate to the distal end at least one of the antegrade probe and the retrograde probe. On the other hand, St. Goar et al. teach a steering mechanism, as recited in column 3, lines 50-55. Thus, it would be obvious to modify the invention of Sterman et al. to have a steering mechanism as taught by St. Goar et al. for the purpose of enhanced movement and more precise location.

Regarding claim 38, Sterman et al. disclose delivering an antegrade probe to a position antegrade to the tissue; delivering a retrograde probe to a position retrograde to the tissue; aligning the first probe and the second probe longitudinally; using one or more of the first and the second probes to stabilize the tissue. However, Sterman et al. do not recite using one or more of the first and the second probes to fasten the tissue. On the other hand, St. Goar et al. teach to fasten tissue. Thus, it would be obvious to one with ordinary skill in the art at the time the invention was made to modify the invention of Sterman et al. with the teachings of St. Goar et al. to incorporate tissue fastening through the probes for the purpose of less invasive procedure. This, combination would yield all of the steps of the method are that completed without arresting the heart.

Regarding claims 39-52, Sterman et al. as modified by St. Goar et al. disclose that as applied to claim 38. Further, the combination would therefore,

also yield that as applied to claims 39-52. See the apparatus rejections stated above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

KO

Henry Bennett
Supervisory Patent Examiner
Group 3700